UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

GIANNA KRSTIC, Plaintiff, v.	Civil Action No. 1:18-cv-11585-NMG
SOFREGEN MEDICAL INC., and ALLERGAN, INC. Defendants.	

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF'S MOTION TO ALTER, AMEND AND VACATE THE DISMISSAL PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 60(b)(1) and (6) and MOTION FOR LEAVE TO AMEND THE COMPLAINT PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 15 (a)(2)

Plaintiff Gianna Krstic, by and through her counsel, moves for Vacation of the Order of Dismissal entered on April 8, 2019[1], of this Action pursuant to Fed. R. Civ. P. 60(b)(1) and (6); opposes Defendant Sofregen Medical Inc.'s Original Motion to Dismiss for the reasons set forth in the accompanying Memorandum of Law and respectfully seeks Leave to Amend her Complaint pursuant to Fed.R.Civ. P. 15(a)(2). The subject of Sofregen's Motion to Dismiss pursuant to Rule 12(b)(6) is the First Amended Complaint, attached as **Exhibit B**. Plaintiff attaches her proposed Second Amended Complaint as **Exhibit C**.

I. VACATION OF THE ORDER OF DISMISSAL AS TO SOFREGEN MEDICAL INC. IS PROPER HERE.

[1] The Order of Dismissal Granting Sofregen's Motion is attached to as **Exhibit D**.

Plaintiff and Defendant Sofregen Medical, Inc. ("Sofregen") have been engaged in discussions concerning dismissal of this matter during the time the motion to dismiss was filed. Plaintiff asked for confidential documentation that supported Sofregen's position that Allergan, the original owner, manufacturer and seller of the subject product, the SERI SCAFFOLD SURGICAL mesh ("SERI" or "silk mesh") had retained liabilities for the product after the sale of the product to Sofregen in November 2016. Sofregen could not or would not produce proof that Allergan had indeed retained the liabilities in the agreement of sale between Allergan and Sofregen. And, Allergan interposed an objection to dismissal of Sofregen through a letter by counsel. As a consequence, Defendant Sofregen agreed not to seek to dismiss the case through April 11, 2019, so that Plaintiff could oppose Sofregen's Rule 12(b)(6) motion. However, due to attorney office mistake, a stipulation and/or leave to file a delayed response to extend the time to respond until April 11, 2019 was not filed with the Court. Therefore, Plaintiff respectfully seeks to vacate the dismissal and reinstate the case and moves for leave to file the Second Amended Complaint which is attached as **Exhibit C**.

II. ALLEGAN INC HAS NOT INTERPOSED AN ANSWER OR MOVED TO DISMISS THE CASE SINCE SETTLEMENT DISCUSSIONS HAVE BEEN ONGOING WITH PLAINTIFF.

Further, during the time period the Motion to Dismiss was pending, Defendant Allergan did not respond to the Complaint per an agreement with Plaintiff because settlement discussions have been underway between Allergan and Plaintiff. Plaintiff has produced thousands of pages of medical records to both Allergan and Sofregan and a detailed demand letter in an attempt to resolve this matter. Allergan's counsel then requested additional records, which Plaintiff supplied. A Copy of all of the medical records and the detailed demand letter was also provided to Sofregen.

Dismissal of the case at this stage is not warranted. First, Sofregen has agreed to delay in Plaintiff's response to its Motion.

And, Allergan has not responded to the Complaint since it has been engaging in settlement discussions. Plaintiff's claims against Allergan should stand because no outstanding Motion was made to dismiss those claims.

Plaintiff attaches the Declaration of Paula Bliss, Esquire as **Exhibit A**.

III. BACKGROUND OF THE CASE

Sofregen is, from all accounts, a one product company formed by a group of businesspersons and scientists financed by a venture capital group to develop this one product: Silk Mesh. Sofregen describes itself as "a force for beauty. We provide plastic surgeons with natural biomaterials to enhance their surgical artistry and achieve more durable results for their patients. We are focused on "silk science for advanced aesthetics" — unlocking the enormous potential of purified silk protein to facilitate soft tissue regeneration for a range of aesthetic procedures and surgery." https://www.sofregen.com/our-story The sole product that Sofregen advertised, promoted and sold was SERI ®SURGICAL SCAFFOLD until 2017, when it introduced another SERI product to its product line. When SERI ®SURGICAL SCAFFOLD was used by a plastic surgeon, Dr. Deirdre Marshall, on beautiful Gianna Krstic, it did nothing more than hideously disfigure her, fail to perform as advertised, scarred her and caused her to suffer serious and life threatening adverse reactions to the silk mesh. Sofregen's SERI ®SURGICAL SCAFFOLD is the subject of this products liability lawsuit. Sofregen seeks to be immunized from liability for this product's failure to perform as promoted and injuries it caused when used as promoted off-label by Sofregen's predecessor in interest, Allergan, Inc.

As a result of the SERI® Surgical Scaffolding's defective nature, including but not limited to, its failure to biodegrade, Ms. Krstic suffered significant injuries, need for additional reconstructive surgeries, which caused disfigurement and harm, the impairment of the use of her right arm, additional medical problems, anxiety, depression, severe emotional pain and distress, and substantial wage loss.

IV. BACKGROUND ON SERI® SURGICAL SCAFFOLDS AND SERI SCAFFOLD SURGERY

SERI® Surgical Scaffold is a silk mesh marketed for use in plastic surgery and reconstructive surgeries to serve as the base for the body to regenerate tissue after medical problems. The sterile product looks similar to a silk screen and can be cut into many shapes and sizes for surgical use without tearing or fraying. Because of its flexibility, Allergan marketed SERI® Surgical Scaffold as useful in laparoscopic surgeries because it easily fit into laparoscopic tools. Serica Technologies originally created the scaffold in the mid-2000s. In 2010, Allergan Inc. acquired Serica Technologies and its scaffold technology.

In November 2016, Sofregen Medical, Inc. purchased the product line in an acquisition said to "strategically [align]" with Sofregen's vision of advancing a variety of silk-based solutions to treat patients with soft-tissue defects. The Chairman of Sofregen Medical, Howard Weisman, referred to the SERI® Surgical Scaffold as "pioneering technology" and remarked on the global market's expectation for products addressing soft-tissue aesthetics to reach $5 billion in 2017. First Am. Cmplt. ¶¶29-35

Sofregen and Allergan represented that the silk Product would not trigger a foreign body immune response. Despite that representation, the Product did trigger a foreign body response in Ms. Krstic. Allergan and Sofregen instructed surgeons to place the scaffold over the area that

needs support such as the bottom and side of the breast in breast-reconstruction surgeries. The surgeon was to place stitches in the scaffold to hold it in place. While in place, the scaffold was represented as having the ability to reinforce and strengthen the patient's soft tissue. As the soft tissue repairs itself post-surgery, it is intended to absorb the silk mesh over time. By the end of the process, the silk scaffold was intended to be mostly or completely reabsorbed by the body and entirely replaced with regrown soft tissue. In places where the silk mesh was not reabsorbed, it was to have significantly degraded and softened. First Am. Cmplt. ¶¶36-37

SERI® Scaffold was market cleared by FDA for "use as a transitory scaffold for soft tissue support and repair to reinforce deficiencies where weakness or voids exist that require the addition of material to obtain the desired surgical outcome."

On May 29, 2015, the FDA issued a Warning Letter to the Quality Assurance Director at Allergan, the manufacturer, distributer, promoter, marketer and seller of SERI® Surgical Scaffolds in the United States. The Warning Letter reported that Allergan was selling these Surgical Scaffolds without marketing clearance or approval by the FDA in violation of the Federal Food, Drug and Cosmetic Act. The Warning Letter indicated Allergan was over marketing its Product, including the general soft tissue reconstruction and soft tissue reinforcement in plastic and reconstructive surgery. FDA stated the breast surgery indication was outside SERI®'s intended use because "surgical mesh has not been cleared or approved for use in breast reconstruction using a tissue expander or implant."

The FDA stated that it had reviewed Allergan's website and found that the SERI® Surgical Scaffold was adulterated and marketed in violation of section 501(f)(1)(B) of the Food, Drug and Cosmetic Act, 21 U.S.C. § 321(h) by Allergan. The FDA found that Allergan was selling the Product in violation of the Act because the Product was misbranded, among other

violations. Sofregen Medical Inc., a Massachusetts privately held corporation acquired SERI® Surgical Scaffolds from Allergan on or about November 14, 2016. First Am. Cmplt. ¶¶7-9

ARGUMENT

I. LEGAL STANDARD

A. Under the Circumstances Preventer, It is Appropriate to Vacate the Order of Dismissal.

Rule 60 of the Fed. R. Civ. P. provides:

Grounds for Relief from a Final Judgment, Order, or Proceeding. On motion and just terms, the court may relieve a party or its legal representative from a final judgment, order, or proceeding for the following reasons:

(1) mistake, inadvertence, surprise, or excusable neglect; .... or

(6) any other reason that justifies relief.

Here, the delay in responding to the motion to dismiss was as a result of mistake, inadvertence, and excusable neglect.

The Court's decision to dismiss the entire case is legally erroneous. First, Plaintiff respectfully submits that the dismissal reflects clerical error. Defendant Sofregen asked that Sofregen be dismissed not that Allergan be Dismissed. And, under the Complaint, Claim One and Two are directed at Allergan. Only Claim Three is directed at Sofregen. Sofregen is liable for its continuous fraudulent concealment of the medical problems caused by the silk mesh at issue in the case. Sofregen acquires the product and responsibility for the product in 2016, two years after Mrs. Krstic was implanted with the silk mesh. By dismissing the entire complaint, the Court inadvertently dismissed the claims against Allergan even though Allergan has not, as yet, interposed an answer to the Complaint. Reinstatement of the action against Allergan in its

entirety is proper. *See Greene v Union Mut. Life Ins. Co. of America*, 764 F.2d 1937,(1st Cir. 1985)

Second, Plaintiff and Defendant Sofregen had agreed that Plaintiff may interpose a response on or before April 11, 2019. Defendant Sofregen agreed not to seek to dismiss for a late response to its Motion to Dismiss, after attempting to negotiate an exchange of information to demonstrate why Sofregen is not liable under these circumstances. Unfortunately, despite bests efforts of counsel, such an agreement could not be reached so then, Sofregen agreed that it would not oppose the delayed response to its Motion to dismiss. Plaintiff's counsel inadvertently failed to alert the Court.

Third, during this time period, Plaintiff and Defendant Allergan have been engaged in settlement discussions. Plaintiff provided hundreds of pages of medical records to both Defendants and provided a very detailed demand letter to both Allergan and Sofregen. Defendant Allergan requested additional information which was also produced to Allergan.

Therefore, the inadvertent failure to apprise the Court of both the settlement negotiations and of the delay in responding to the motion to dismiss does not prejudice the defendants and therefore, Plaintiff respectfully seeks vacation of the dismissal and reinstatement of her action.

B. The Complaint Should Not Be Dismissed under Rule 12(b)(6).

A complaint should be dismissed under Rule 12(b)(6) only where it appears that the facts alleged fail to state a "plausible" claim for relief. *See Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555-56 (2007). A complaint may survive a motion to dismiss, however, even if it is "improbable" that a plaintiff would be able to prove those facts and even if the possibility of recovery is extremely "remote and unlikely." *Id.* at 556 (citations and quotations omitted). A claim is plausible where the plaintiff alleges factual content that "allows the court to draw the

reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

When considering a 12(b)(6) motion to dismiss, the Court must "accept as true all factual statements alleged in the complaint and draw all reasonable inferences in favor of the non-moving party." *McCarthy v. Dun & Bradstreet Corp.*, 482 F.3d 184, 191 (2d Cir.2007). Moreover, the federal pleading rules do not countenance dismissal of a complaint for an imperfect statement of the legal theory supporting the claim asserted. See *Johnson v. City of Shelby, Miss.*, 135 S. Ct. 346, 346 (2014) (per curiam).

"The function of a motion to dismiss is 'merely to assess the legal feasibility of the complaint, not to assay the weight of the evidence which might be offered in support thereof.'" *Mytych v. May Dept. Stores Co.*, 34 F. Supp.2d 130, 131 (D.Conn.1999), quoting *Ryder Energy Distribution v. Merrill Lynch Commodities, Inc.*, 748 F.2d 774, 779 (2d Cir.1984). "The issue on a motion to dismiss is not whether the plaintiff will prevail, but whether the plaintiff is entitled to offer evidence to support his claims." *United States v. Yale New Haven Hosp.*, 727 F. Supp. 784, 786 (D.Conn.1990) (citations omitted).

To survive a motion to dismiss for failure to state a claim under Fed. R.Civ.P. 12(b)(6), the claim for relief must contain "sufficient factual matter" such that it is actionable as a matter of law and "plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 667, 129 S.Ct. 1937, 173 L.Ed.2d 868(2009) (quoting *Bell Alt. Corp. v. Twombly*, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007). A claim is factually plausible if, after accepting as true all non-conclusory factual allegations, the court can draw the reasonable inference that the defendant is liable for the misconduct alleged. *Ocasio-Hernandez v. Fortuno-Burset*, 640 F.3d 1, 12 (1st Cir. 2011).

First and foremost, Sofregen seeks to dismiss this case without any discovery on particularly difficult questions: whether Sofregen can be held responsible for the defective product it acquired from Allergan, and whether the claims against Sofregen are preempted. **It is premature**

II. CONFLICT OF LAWS

A. Plaintiff agrees that Florida Law Applies to the Torts at Issue in this Case.

Jurisdiction of this Court in this matter is based upon diversity pursuant to 28.U.S.C. §1332. Plaintiff is a North Carolina resident and citizen, Sofregen is headquartered in Massachusetts, and Allergan is headquartered in California. First Am. Cmplt. ¶¶10-12 Both Sofregen and Allergan were incorporated in Delaware.

A federal court sitting in diversity must apply the conflict of law rules of the state in which it sits. *Klaxon Co. v. Stentor Elec. Manuf. Co.*, 313 U.S. 487, 61 S.Ct. 1020, 85 L.Ed. 1477 (1941); *Crellin Technologies, Inc. v. Equipment Lease Corp.*, 18 F.3d 1, 4 (1st Cir.1994). Under Massachusetts choice of law rules, tort claims are governed by the law of the state in which the injury occurred, unless another state has a more significant relationship to the underlying cause of the case. *Bergin v. Dartmouth Pharm., Inc.,* 326 F. Supp. 179,183 (D. Mass. 2004). Here, Florida law applies. Allergan, through its sales representatives and marketing teams promoted and sold the SERI SURGICAL SCAFFOLD to be used off-label by plastic surgeons such as Dr. Marshall, the implanting physician in Miami, Florida. The procedure was performed in Miami and the injuries occurred in Florida. Therefore, under the Massachusetts choice of law rules, Florida laws should apply to the torts at issue in this case. *Bergin v. Dartmouth, supra.*; *Asymmetrix Medical, Inc., et al. v. McKeon*, 932 F. Supp. 232 (D. Mass. 2013)(Gorton, J.).

B. Delaware Law Does Not Apply to the Question of Successor-in-Interest Because Delaware Law is the Same as Massachusetts Law on the Question of Successor Liability in Connection with the Product Line Theory.

Defendant Sofregen suggests that that Massachusetts choice of law rules must apply to the determination of whether or not Sofregen, as the successor in ownership of SERI, is responsible for torts that occurred as a result of use of the product earlier than its acquisition of SERI. As this Court is aware, the Court sitting in diversity must first determine which state's substantive law governs. *See Garcia v. Plaza Oldsmobile Ltd.*, 421 F.3d 216, 219 (3d Cir.2005). *See Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487, 496, 61 S.Ct. 1020, 85 L.Ed. 1477 (1941); *Yohannon v. Keene*, 924 F.2d 1255, 1264 (3d Cir.1991). Defendant Sofregen is correct that because choice of law analysis is issue-specific, differing states' laws may apply to different issues in a single case, a principle known as "depecage." See, e.g., *Compagnie des Bauxites v. Argonaut–Midwest Ins. Co.*, 880 F.2d 685, 691 (3d Cir.1989). And, Plaintiff agrees that Florida law applies to her tort claims. But, Plaintiff does not agree that Delaware law applies to the question of successor in interest.

Initially, however, the Court must determine whether a true conflict exists between the application of Massachusetts law, Florida law or, as Defendant suggests, Delaware law. According to conflicts of law principles, where the laws of the different jurisdictions would produce the same result on the particular issue presented, there is a "false conflict," and the Court should avoid the choice-of-law question entirely. *See Williams v. Stone*, 109 F.3d 890, 893 (3d Cir.1997); *Lucker Mfg. v. Home Ins. Co.*, 23 F.3d 808, 813 (3d Cir.1994) (applying Pennsylvania choice-of-law rules). If this Court determines that there is no material difference between Massachusetts and Florida and Delaware successor liability law, then, the Court need not decide which state's law governs the successor liability issue.

The ordinary rule of successor liability is rooted in corporate law, and it states that a firm that buys assets from another firm does not assume the liabilities of the seller merely by buying its assets. See, e.g., *Luxliner P.L. Export Co. v. RDI/Luxliner, Inc.*, 13 F.3d 69 (3d Cir.1993); *Polius v. Clark Equip., Co.*, 802 F.2d 75 (3d Cir.1986) (noting that the general rule of corporate successor liability was "designed for the corporate contractual world where it functions well"); 15 William Meade Fletcher et al., Fletcher Cyclopedia of the Law of Private Corporations § 7122. The problem of characterization lies in the mottled nature of the exceptions to the ordinary rule in successor liability law because they are not uniformly characterized as wholly based in tort, contract, or corporate law. *See, e.g., United States v. General Battery Corp.*, 423 F.3d 294, 301 (3d Cir.2005) (noting that the choice of law framework governing successor liability remains "unsettled"); *Savage Arms, Inc. v. Western Auto Supply Co.*, 18 P.3d 49, 53 (Alaska 2001) (analyzing other states' approaches to successor liability law and concluding that successor cases dealing with products liability are appropriately characterized as torts questions); *Ruiz*, 89 F.3d at 326 (noting that many courts have "struggled to decide whether [successor liability] is part of corporate law or tort law"); *Webb v. Rodgers Mach. Mfg. Co.*, 750 F.2d 368, 374 (5th Cir.1985); *In re Asbestos Litigation (Bell)*, 517 A.2d 697, 699 (Del.Super.1986) (holding that contract/corporate law applied to successor liability case based on legal effect of contract between corporations).

While the basic tenet of successor liability law is based in corporate law, the exceptions span a loose substantive continuum from contract to corporate to tort law. There are four traditional exceptions, all founded in corporate and contract law. See *Ruiz,* 89 F.3d at 326. The first exception covers situations where the buyer either expressly or implicitly agrees to assume some or all of the seller's liabilities. It is usually straightforward in application. Because this

exception is based on interpreting the terms of the parties' agreement, it is characterized most strictly as contract law. See, e.g., *T.H.S. Northstar Associates v. W.R. Grace & Co.*, 840 F.Supp. 676, 677–78 (D.Minn.1993) (indicating that the Court would enforce the contractual choice of law clause under an "express assumption of liability" theory of successor liability). Here, since discovery has not yet commenced, we do not know if this exception applies.

The second exception applies where a transaction is entered into fraudulently in order to evade liability. The third and fourth exceptions, *de facto* merger and mere continuation, are generally treated identically, see, e.g., *Luxliner*, 13 F.3d at 73 (stating that "[m]uch the same evidence is relevant to each determination," and listing the same factors as necessary to determine "whether either of these exceptions applies"), as both arise where there is continuity of identity between the buyer and seller, see *Ruiz*, 89 F.3d at 325 ("In effect, the de facto merger and continuation exceptions are identical; each exception depends upon an identity of ownership between the seller and purchaser"). "Mere continuation" analysis focuses on whether the new corporation is merely a restructured form of the old, while de facto merger analysis inquires whether a transaction—though structured as an asset purchase—factually amounts to a consolidation or merger.

Additionally, many states have adopted rules expanding successor liability in products liability cases. See *Dawejko v. Jorgensen Steel Co.*, 290 Pa.Super. 15, 434 A.2d 106, 111 (1981); *Ramirez v. Amsted Industries, Inc.*, 86 N.J. 332, 431 A.2d 811, 824–825 (1981); see also *Ray v. Alad Corp.*, 19 Cal.3d 22, 136 Cal.Rptr. 574, 560 P.2d 3 (1977) (departing, for the first time, from traditional corporate law grounding of successor liability).

Under the so-called "product line" theory, the successor corporation remains strictly liable in tort for the defective products of its predecessor. Thus, at one extreme lies the explicit

and implicit assumption of liability exception, interpreted solely based on contract. At the other, lies the product line exception, which is generally analyzed using torts choice of law principles.

Delaware courts recognize successor liability as a viable legal theory and, as well, that there are exceptions to the general principle that purchasers of assets do not succeed to a seller's liability. *Fehl v. S.W.C. Corp.*, 433 F.Supp. 939, 945 (D. Del.1977). Over the years, however, various courts have constructed several exceptions to this rule. These exceptions are the same as the exceptions found under Massachusetts law.

The Delaware District Court, applying Delaware law, has opined that "in some limited situations where an avoidance of liability would be unjust, a purported sale of assets for cash or other consideration may be found to transfer liabilities of the predecessor corporation." *Fehl*, 433 F.Supp. at 945. Thus, it is apparent that the rule whereby a purchasing corporation is obligated to only those liabilities which it expressly assumes is not absolute.

Accordingly, theories exist upon which Sofregen may be held liable for the obligations of Allergan in connection with the SERI product, whether or not Defendant did not expressly assume these liabilities pursuant to the asset transfer. *Knapp* and *Fehl* cases cited above are products liability cases. None of the cases cited by Defendant expressly state nor even focus on the fact that the exceptions to a successor corporation's assumption of liabilities are applicable only to liabilities related to defective products. Rather, the rationale behind those cases, that a corporation, under the guise of an asset transfer, should not be permitted to take over the essence of another corporation-that is, essentially merge with that other corporation-yet avoid certain liabilities of the predecessor corporation which it does not wish to assume, applies equally to tort and non-tort cases alike.

Undeniably, to prevail on such a theory, Plaintiff must meet the rigorous standard of showing that Sofregen is a "continuation" of Allergan in connection with the manufacture, sale and continued promotion of the SERI product. Based upon Plaintiff's showing of a certain set of facts in the Amended Complaint before this Court, a theory exists upon which Plaintiff Gianna Krstic may be able to hold Defendant Sofregen liable under Florida law. Such a finding is all that is required to withstand a Rule 12(b)(6) motion to dismiss. *Corporate Property Associates 8, LP v. Amersig Graphics* (unreported op.), 2014 WL 148269 (Del. Chancery Court 1994).

C. Plaintiff has set forth Sufficient Facts to Make out Her Claims against Sofregen.

The gravamen of Defendant's argument is simply that as successor in interest to this product, it cannot be held liable for the Product's defective and dangerous nature. Because this is a product liability action, successor s in interest may be held liable for the product's defects under Massachusetts law as well as under Florida law and Delaware law. Without discovery, Plaintiff cannot represent more facts. These defenses are premature at this point.

D. The Claims against Sofregen are Not Preempted.

Through the Medical Device Amendments ("MDA"), Congress established a three-tiered system for federal oversight of medical devices. The SERI SCAFFOLD is not the subject to the highest level of federal oversight. 21 U.S.C. § 360c(a)(1)(C)(ii)(II).

The core set of operative facts supporting Ms. Krstic's cause of action, and all of the legal theories flowing therefrom, is the Defendant's off-label marketing of a dangerous device, dissemination of false and misleading marketing materials. The authority from the Supreme Court leads inexorably to the conclusion that the Plaintiff's claims are not preempted. In May, 2015, after the device was implanted into Ms. Krstic, the he Food and Drug Administration issued a warning to Allergan Inc., the manufacturer of the Seri Surgical Scaffold Device, that

marketing their products for breast surgery indications had not yet received approval or clearance by the federal agency. This came after the agency reviewed the company's website and found the scaffold was being marketed for off-label breast surgery applications. The Food and Drug Administration concluded that the issues "would constitute a major change in its modification to its intended use, for which your firm lacks clearance or approval." The federal agency reminded the manufacturer that breast surgery indication was not be approved the intended use of the surgical mesh device because the product "has not been cleared or approved for use in breast reconstruction using tissue expander or implant." Instead, clearance for the product was approved because it could be used "as a transitory scaffold for soft tissue support and repair to reinforce deficiencies where weakness or voids exist that require the addition of material to obtain the desired surgical outcome." The FDA in their letter was referring to indications as soft-tissue reinforcement and general soft-tissue reconstruction that is often necessary for reconstructive or plastic surgeries. Here, the device was used as a complete scaffold for Ms. Krstic's breast reconstruction, a use that was specifically not indicated in the approval by FDA.

Under Florida law, there is no wholesale preemption for claims against manufacturers of devices cleared through 5the 510(k) process. Therefore, Defendants' wholesale argument that all of Plaintiffs' claims are preempted is not well-founded, and the motion to dismiss on this basis should be denied.

1. THE MEDICAL DEVICE AMENDMENTS

The Medical Device Amendments of 1976, 21 U.S.C. § 360c et seq., were enacted to amend the FDA's enabling statute, the Food, Drug, and Cosmetic Act, id. § 301 et seq. The Medical Device Amendments gave the FDA regulatory authority over medical devices for human use. See § 360c et seq. Under that authority, the FDA classifies medical devices into three

categories, depending on the level of risk presented. See *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316–17, 128 S.Ct. 999, 1003, 169 L.Ed.2d 892 (2008). But, the device at issue here is not a Class III device requiring these protections. See id.; 21 U.S.C. § 360c(a)(1); 21 C.F.R. § 888

Premarket approval is a rigorous process of federal review that evaluates a medical device's safety and effectiveness. *See Riegel*, 552 U.S. at 317–20, 128 S.Ct. at 1004–05 (describing this process). This process takes, on average, about 1,200 hours of review by the FDA. *Id.* at 318, 128 S.Ct. 999. For each device, the FDA compiles a large amount of data and carefully weighs the risks and benefits. *See id.* Even once approved, the FDA regularly attaches specific conditions to a device. See id. at 319, 128 S.Ct. 999; 21 U.S.C. § 360j(e)(1). And after the FDA approves a device, the manufacturer may not make any change to the device's specifications, or anything else that might affect its safety and effectiveness, unless it submits a supplemental application to the FDA. 21 U.S.C. § 360e(d)(5)(A)(i). The FDA must be informed of changes to the manufacturing process. *Id.* The manufacturer must report information to the FDA, including new studies about the device and any adverse events. Id. § 360i; 21 C.F.R. §§ 803.50(a), 814.84(b)(2).

However, a 510(k) device, like the one at issue here, does not go through the same rigorous process. The same legal protections do not apply. The 510(k) review process originates from the Medical Device Amendments of 1976 (MDA) to the Federal Food, Drug, and Cosmetic Act. The MDA was enacted in order to "impose[ ] a regime of detailed federal oversight" of medical devices. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316, 128 S.Ct. 999, 169 L.Ed.2d 892 (2008). Under the MDA, certain devices must complete a thorough premarket approval (PMA) process with the FDA before they may be marketed, including all devices that cannot "provide reasonable assurance of the[ir] safety and effectiveness" under less stringent

scrutiny, and that are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health" or "present[ ] a potential unreasonable risk of illness or injury." *Id.* at 317, 128 S.Ct. 999; 21 U.S.C. § 360c(a)(1)(C). The PMA process requires the applicant to demonstrate a "reasonable assurance" that the device is both "safe ... [and] effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001); 21 U.S.C. § 360e(d)(2)(A), (B).

An exemption to the PMA requirement exists for medical devices that were already on the market prior to the MDA's enactment in 1976; these devices are allowed to remain on the market until the FDA initiates and completes PMA review for them. See 21 U.S.C. § 360e(b)(1)(A); *Buckman*, 531 U.S. at 345, 121 S.Ct. 1012. In order to ameliorate the monopolistic consequences of this exemption, the MDA also allows other manufacturers to market devices that are shown to be "substantially equivalent" to pre–1976 devices that are exempt from the PMA requirement. *Buckman*, 531 U.S. at 345, 121 S.Ct. 1012 (citing § 360e(b)(1)(B)). The 510(k) process is the method by which a manufacturer demonstrates substantial equivalence. *Id.*

Notably, the PMA and 510(k) processes have distinct requirements and different goals. PMA "is federal safety review," *Riegel*, 552 U.S. at 323, 128 S.Ct. 999, whereas "the 510(k) process is focused on equivalence, not safety," *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996) (quotation omitted and alteration adopted). Indeed, "devices that enter the market through § 510(k) have never been formally reviewed ... for safety or efficacy." *Riegel*, 552 U.S. at 323, 128 S.Ct. 999 (quotation omitted). Rather, the 510(k)

exemption is "intended merely to give manufacturers the freedom to compete, to a limited degree, with and on the same terms as manufacturers of medical devices that existed prior to 1976." *Lohr*, 518 U.S. at 494, 116 S.Ct. 2240.

These differences are reflected in the intensity of review: "[I]n contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in an average of only 20 hours." Id. at 479, 116 S.Ct. 2240; see also *Goodlin v. Medtronic, Inc.,* 167 F.3d 1367, 1369 n.1 (11th Cir. 1999) ("[T]he FDA completes the average 510k review within 20 hours, and the agency considers only whether the device is indeed the equivalent of a preexisting device—regardless of how unsafe or ineffective the grandfathered device happens to be."). The two processes are "by no means comparable." *Lohr,* 518 U.S. at 478, 116 S.Ct. 2240.

The 510(k) review process is not relevant to a product's safety. As such, the claims against the manufacturer of the product for negligence and failure to warn are not preempted as they would be in the context of a PMA approved device. *Id. See Eghnayem v. Boston Scientific,* 873 F.3d 1304 (11th Cir. 2017)(applying Florida law).

E. There is a Clear Chain of Causation.

In order to make out a successful failure to warn theory, the evidence must establish two elements: "A plaintiff seeking to recover damages for the failure to warn must prove that the defendant (1) is a manufacturer or distributor of the product at issue, and (2) did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of the manufacture and distribution. *Thomas v. Bombardier Recreational Prods., Inc.* 682 F.Supp.2d 1297, 1300 (M.D.Fla.2010). The plaintiff must also establish that the inadequate warning was a proximate

cause of her injury. *Hoffmann La Roche, Inc. v. Mason*, 27 So.3d 75, 77 (Fla. 5th DCA 2009)" *Small v Amgen*, 134 F. Supp. 3d. 1358, 1366-67 (MDFL 2015).

Here, Plaintiff plausibly alleges that the requisite causal nexus between Defendants' violation of this duty to report adverse events by the MDRs, and the Plaintiffs' injuries. Section 360k protects a medical device manufacturer from liability only "to the extent that it has complied with federal law, but it does not extend protection from liability where the [state tort] claim is based on a violation of federal law." *Bausch v. Stryker Corp.*, 630 F.3d at 552. Plaintiff has alleged that Defendants violated state tort law, namely, by failing to warn physicians about the risks of the SERI product because of the undisclosed dangers of use of the product. It is because of this simple fact—that Plaintiff's cause of action is a traditional state failure to warn theory and negligence—that it is not preempted. Plaintiff's claim survives implied preemption in addition to express preemption.

The SAC adequately states a claim that the SERI SURGICAL SCAFFOLD was defective on a failure to warn theory. It is alleged that Defendants were aware of adverse events associated with the use of SERI —instances in which it malfunctioned and posed a danger to patients— and that it did not warn the FDA and the general public about this danger, concealing information Defendants were required to report, thereby putting potential users at risk from the danger it posed. Specifically, Defendants put Ms. Krstic at risk for precisely the dangers with the device that she caused her injuries for which she continues to suffer.

III. THE MOTION FOR LEAVE TO AMEND THE COMPLAINT PURSUANT TO RULE 15(a)(2) SHOULD BE GRANTED.

Plaintiff moves to amend her complaint to address certain issues raised by

Sofregen in its motion to dismiss. Sofregen is correct that the Massachusetts Consumer Protection Act claim does not apply, since the device was sold in Florida. For all of these reasons, leave to file the Second Amended Complaint should be permitted.

IV. CONCLUSION

For all the reasons as set forth in the accompanying Memorandum of Law, Plaintiff respectfully requests that this Court grant the Motion to Vacate the Order of Dismissal, deny Sofregen's Motion to Dismiss and Grant Plaintiff's Motion for Leave to file the Second Amended Complaint.

GIANNA KRSTIC,
By Her Attorney,

Dated: April 10, 2019

/s/ Paula S. Bliss

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on April 10, 2019.

/s/ Paula S. Bliss